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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,351	09/30/2003	Ye Fang	SP03-121	7131

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EXAMINER
VENCI, DAVID J

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/676,351	FANG ET AL.	
	Examiner	Art Unit	
	David J. Venci	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *February 24, 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *11,12 and 16-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10 and 13-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *September 30, 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 6-7-04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicant's election with traverse of Group I, claims 1-15, in the reply filed on February 24, 2005. In addition, Examiner acknowledges Applicant's species election with traverse of "BSA," readable on claims 1-10 and 14-15. The traversal is on the grounds that a simultaneous examination does not impose a serious burden upon Examiner because all of the claims in Groups I, II and III relate to buffer solutions or uses thereof. Applicants' argument has been carefully considered but is not persuasive because most of the biomedical prior art also relates to buffer solutions or uses thereof. In addition, there is no apparent relationship in the prior art among solutions containing the recited species. For example, there is no apparent relationship in the prior art between solutions containing dextran, versus solutions containing dry milk. The seemingly disparate uses for solutions containing the recited species would necessitate an exceedingly broad search involving separate searches of multiple branches of prior art biomedical literature for each species. The requirement is deemed proper and is made FINAL.

Currently, claims 1-10 and 13-15 are under examination.

Drawings

The drawings are objected to because the microarray images and graphs have poor resolution. For example, the microarray images in Figs. 2A and 2B are depicted as solid black squares. In Figs. 3C and 3D, both bars on each graph are solid black. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended

replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-10 and 13-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Throughout the claims, the recitation of "about" renders the scope of the affected claims indefinite because the numerical range of "about" is not clear.

In claim 1, the recitation of "the solution having a composition" is indefinite because it is not clear whether "composition" describes the makeup of the solution, or whether "composition" describes a product that is separate and distinct from the solution. In addition, the recitation of "pH in the range of bout 6.5 to about

7.9" is indefinite because it is not clear whether said pH range represents the final pH of the buffered solution. In addition, the recitation of "optionally" is indefinite because it is not clear whether verbiage subsequent to "optionally" contains required claim limitations. In addition, the recitation of "0.01 wt.% to about 2 wt.% of the composition" is indefinite because it is not clear whether "0.01 wt.% to about 2 wt.% of the composition" describes the concentration of blocker reagent in the solution, or whether "0.01 wt.% to about 2 wt.% of the composition" describes the mass percentage of blocker reagent in the composition. In addition, the recitation of "or both c) and d)" appears grammatically awkward or misplaced.

In claim 7, the recitation of "said pH buffer" lacks antecedent basis. In addition, the term "commonly used" is a relative term that renders the claim indefinite. The term "commonly used" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree of commonality, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

In claim 8, the recitation of "may be" is indefinite because it is not clear whether language subsequent to "may be" contains required claim limitations.

Claim 9 is missing a "." at the end of the claim.

In claim 10, the recitations of "said blockers", "the binding" and "the probe receptor" lack antecedent bases. In addition, the recitation of "said blockers characterized as a reagent" appears grammatically awkward.

In claim 13, the recitation of "wherein said water-soluble protein is... dry milk" is indefinite because it is not clear how whether/how "dry milk" is a protein.

In claim 14, the recitation of "said solution" lacks antecedent basis.

In claim 15, the terms "sulforyl" and "ethylmaleimid" appear misspelled.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-10 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hawes & van Biesen, CURRENT PROTOCOLS IN PHARMACOLOGY, Unit 3.5 (1999), in view of Boehringer Mannheim Corp., *1998 Biochemicals Catalog*, pp. 486-493 (1998).

Hawes & van Biesen describe a buffered solution (see p. 3.5.11, REAGENTS AND SOLUTIONS, "*Assay buffer 1*") comprising a buffer reagent with a pH between 6.5 and 7.9 (see p. 3.5.11, REAGENTS AND SOLUTIONS, *Assay buffer 1*, "Tris-Cl, pH 7.4"), a monovalent inorganic salt at a concentration between 1-500 mM (see p. 3.5.11, REAGENTS AND SOLUTIONS, *Assay buffer 1*, "100mM $NaVO_3$"), a divalent inorganic salt at a concentration between 1-500 mM (see p. 3.5.11, REAGENTS AND SOLUTIONS, *Assay buffer 1*, "10mM $MgCl_2$"), a blocker reagent at a concentration between 0.01% to 2% (see p. 3.5.11, REAGENTS AND SOLUTIONS, *Assay buffer 1*, "0.1 mg/ml BSA"), and a protease-inhibitor (see p. 3.5.13, *Critical Parameters*, second paragraph, "protease inhibitors in the lysis and assay buffers", see Table 3.5.3).

Hawes & van Biesen do not teach a specific concentration of 0.001-100 mM used for the protease-inhibitor.

However, Boehringer Mannheim Corp. teaches a protease-inhibitor concentration of 0.001-100 mM (see pp. 486-487, *Suggested Starting Concentrations*). Therefore, it would have been obvious for a person of ordinary skill in the art to provide the buffered solution of Hawes & van Biesen with a protease-inhibitor concentration of 0.001-100 mM because Hawes & van Biesen instruct readers to use protease inhibitors from Boehringer Mannheim Corp. and Boehringer Mannheim Corp. explicitly suggests protease-inhibitor concentration of 0.001-100 mM.

With respect to claim 6, Hawes & van Biesen describe a buffered solution further comprising a labeled ligand (see p. 3.5.11, REAGENTS AND SOLUTIONS, *ATP mix*, "[γ-^{32}P]ATP") and a target compound (see p. 3.5.5, DETECTION OF TRANSPHOSPHORYLATION OF EXOGENOUS SUBSTRATES, *Materials*, "angiotensin II peptide").

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-5, 7-10 and 13-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-5 and 10-12 of copending Application No. 10/651554. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending Application No. 10/651554 also claims a buffered solution comprising a buffer reagent (see claim 1, "pH buffer reagent") with a pH between 6.5 and 7.9 (see claim 1, "pH from about 5.8 to about 7.8"), a monovalent inorganic salt at a concentration between 1-500 mM (see claim 1, "monovalent or divalent, inorganic salt at a concentration of bout 1mM to about 500mM"), a divalent inorganic salt at a concentration between 1-500 mM (see claim 1, "monovalent or divalent, inorganic salt at a concentration of bout 1mM to about 500mM"), a blocker reagent at a concentration between 0.01% to 2% (see claim 1, "water-soluble protein at a concentration of about 0.01% to 3%", see claim 11, "bovine serum albumin"), and a protease-inhibitor (see claim 1, "protease inhibitor at a concentration of bout 0.01 mM to about 100 mM").

Claim 6 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4-5 and 10-12 of copending Application No. 10/651554 in view of Hawes & van Biesen, CURRENT PROTOCOLS IN PHARMACOLOGY, Unit 3.5 (1999).

Application No. 10/651554 claims a buffered solution as substantially described supra. Application No. 10/651554 does not claim a labeled ligand or a target compound.

However, Hawes & van Biesen describe a buffered solution comprising a labeled ligand (see p. 3.5.11, REAGENTS AND SOLUTIONS, *ATP mix*, "[γ-^{32}P]ATP") and a target compound (see p. 3.5.5, DETECTION OF TRANSPHOSPHORYLATION OF EXOGENOUS SUBSTRATES, *Materials*, "angiotensin II peptide"). Therefore, it would have been obvious for a person of ordinary skill in the art to provide the buffered solution as

claimed in Application No. 10/651554 with the added ingredients of a labeled ligand or a target compound because Hawes & van Biesen teach buffered solutions containing a labeled ligand and a target compound can be used to detect and quantify tyrosine kinases that mediate the enzymatic transfer of the γ phosphate of ATP to the phenolic groups of tyrosine residues (see p. 3.5.1).

These are provisional obviousness-type double patenting rejections.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J Venci
Examiner
Art Unit 1641

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04/17/07